

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Takashi Tsuji et al.                      Art Unit :  
Serial No. :    Examiner :  
Filed : Herewith  
Title : HUMAN MONOCLONAL ANTIBODY AGAINST A COSTIMULATORY  
SIGNAL TRANSDUCTION MOLECULE AILIM AND PHARMACEUTICAL  
USE THEREOF

**MAIL STOP PATENT APPLICATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Under 35 U.S.C. § 120, this application relies on the earlier filing date of U.S. Application Number 09/859,053, filed on May 16, 2001. The references listed on the enclosed form PTO-1449 were submitted to and/or cited by the Office in the prior application and, therefore, are not provided in this application.

Applicants also wish to bring to the Examiner's attention the following co-pending applications, which are assigned to the assignee of the present application and contain at least one overlapping inventor with the present application:

U.S. Application No. 09/383,551, filed August 26, 1999;  
U.S. Application No. 09/561,308, filed April 28, 2000;  
U.S. Application No. 10/107,828, filed March 26, 2002;  
U.S. Application No. 10/107,868, filed March 26, 2002;  
U.S. Application No. 10/107,907, filed March 26, 2002;  
U.S. Application No. 10/301,056, filed November 21, 2002;  
U.S. Application No. 10/729,880, filed December 5, 2003;  
U.S. Application No. 09/859,053, filed May 16, 2001;  
U.S. Application No. 10/625,105, filed July 22, 2003;  
U.S. Application No. 10/704,426, filed November 7, 2003;  
U.S. Application No. 10/704,030, filed November 7, 2003;

CERTIFICATE OF MAILING BY EXPRESS MAIL

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March 10, 2004  
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Attorney's Docket No.: 14539-006003 / JF-93US-D2

U.S. Application No. 10/704,072, filed November 7, 2003;  
U.S. Application No. 10/704,056, filed November 7, 2003;  
U.S. Application No. 10/723,602, filed November 25, 2003; and  
U.S. Application No. 10/721,404, filed November 25, 2003.

This statement is being filed with the application. Please apply any charges or credits to  
Deposit Account No. 06-1050, referencing Attorney Docket No. 14539-006003.

Respectfully submitted,

Date: March 10, 2004

  
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Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. <b>14539-006003</b>	Application No.
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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,506,126	4/9/1996	Seed et al.			
	AB	5,521,288	5/28/1996	Linsley et al.			
	AC	5,914,112	06/22/1999	Bednar et al.			
	AD	6,075,181	6/13/2000	Kucherlapati et al.			
	AE	2002/0156242	10/24/2002	Tamatani et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AF	WO 97/26912	07/31/1997	WIPO				
	AG	WO 98/11909	03/26/1998	WIPO				
	AH	WO 98/37415	08/27/1998	WIPO				
	AI	WO 98/38216	09/03/1998	WIPO				
	AJ	WO 98/45331	10/15/1998	WIPO				
	AK	WO 99/15553	04/01/1999	WIPO				
	AL	WO 00/19988	04/13/2000	WIPO				
	AM	WO 00/46240	08/10/2000	WIPO				
	AN	WO 00/67788	11/16/2000	WIPO				
	AO	WO 01/08700	02/08/2001	WIPO				
	AP	WO 01/12658	02/22/2001	WIPO				
	AQ	WO 01/15732	03/08/2001	WIPO				
	AR	WO 01/18022	03/15/2001	WIPO				
	AS	WO 01/21796	03/29/2001	WIPO				
	AT	WO 01/32675	05/10/2001	WIPO				
	AU	WO 01/64704	09/07/2001	WIPO				
	AV	WO 01/87981	11/22/2001	WIPO				
	AW	WO 02/44364	06/06/2002	WIPO				
	AX	WO 02/70010	09/12/2002	WIPO				

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							Yes	No
	AY	WO 02/76504	10/03/2002	WIPO				
	AZ	AU 13320/99	04/12/1999	AU				
	AAA	DE 19821060	04/15/1999	DE				
	ABB	EP 0984023 A1	03/08/2000	EP				
	ACC	EP 1 125 585 A1	08/22/2001	EP				

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	ADD	Aicher et al., "Characterization of Human Inducible Costimulator Ligand Expression and Function," J. IMMUNOL., 164(9):4689-4696 (2000)
	AEE	Bajorath, "A molecular model of inducible costimulator protein and three-dimensional analysis of its relation to the CD28 family of T cell-specific costimulatory receptors," J. MOL. MODEL 5:169-176 (1999)
	AFF	Beier et al., "Induction, binding specificity and function of human ICOS," EUR. J. IMMUNOL., 30(12):3707-3717 (2000)
	AGG	Bensimon et al., "Human lupus anti-DNA autoantibodies undergo essentially primary V kappa gene rearrangements," EMBO J. 13(13):2951-62 (1994)
	AHH	Brodie et al., "LICOS, a primordial costimulatory ligand?," CURR. BIOL., 10(6):333-336 (2000)
	AII	Buonfiglio et al., "Characterization of a novel human surface molecule selectively expressed by mature thymocytes, activated T cells and subsets of T cell lymphomas," EUR. J. IMMUNOL., 29(9):2863-2874 (1999)
	AJJ	Buonfiglio et al., "The T cell activation molecule H4 and the CD28-like molecule ICOS are identical," EUR. J. IMMUNOL. 30(12):3463-3467 (2000)
	AKK	Cameron "Recent advances in transgenic technology" MOLECULAR BIOTECHNOLOGY 7:253-65 (1997)
	ALL	Chambers, "The expanding world of co-stimulation: the two-signal model revisited," TRENDS IN IMMUNOLOGY, 22(4):217-223 (2001)
	AMM	Cocks et al., "A novel receptor involved in T-cell activation," NATURE, 376:260-263 (1995)
	ANN	Coyle et al., "The CD28-Related Molecule ICOS Is Required for Effective T Cell-Dependent Immune Responses," IMMUNITY 13(1):95-105 (2000)
	AOO	Dong et al., "Cutting Edge: Critical Role of Inducible Costimulator in Germinal Center Reactions," J. IMMUNOL., 166(6):3659-3662 (2001)
	APP	Dong, "ICOS co-stimulatory receptor is essential for T-cell activation and function," NATURE 409(6816):97-101 (2001)
	AQQ	Goni et al., "Structural and idiotypic characterization of the L chains of human IgM autoantibodies with different specificities," J. Immunol. 142(9):3158-63 (1989)

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	ARR	Gonzalo et al., "Cutting Edge: The Related Molecules CD28 and Inducible Costimulator Deliver Both Unique and Complementary Signals Required for Optimal T Cell Activation," J. IMMUNOL., 166(1):1-5 (2001)
	ASS	Guo et al., "Stimulatory Effects of B7-Related Protein-1 on Cellular and Humoral Immune Responses in Mice," J. IMMUNOL., 166(9):5578-5584 (2001)
	ATT	Hanzawa et al., "Characteristics of a TTH1 antibody which blocks an unknown adhesion phenomenon," PROCEEDINGS OF THE JAPANESE SOCIETY FOR IMMUNOLOGY, Vol. 24, Abstract No. W17-13 (1994) [ORIGINAL JAPANESE AND ENGLISH LANGUAGE TRANSLATION]
	AUU	Heyeck et al., "Developmental regulation of a murine T-cell-specific tyrosine kinase gene, Tsk," PROC. NATL. ACAD. SCI. USA, 90:669-673 (1993)
	AVV	Houdebine "Production of pharmaceutical proteins from transgenic animals" J. BIOTECHNOL. 34:269-87 (1994)
	AWW	Hutloff et al., "ICOS is an inducible T-cell co-stimulator structurally and functionally related to CD28," NATURE, 397(6716):263-266 (1999)
	AXX	Ishikawa et al., "Prediction of the Coding Sequences of Unidentified Human Genes. X. The Complete Sequences of 100 New cDNA Clones from Brain Which Can Code for Large Proteins <i>in vitro</i> ," DNA RESEARCH, 5:169-176 (1998)
	AYY	Kappel et al. "Regulating gene expression in transgenic animals" CURRENT OPINION IN BIOTECHNOLOGY 3:548-53 (1992)
	AZZ	Kopf et al., "Inducible Costimulator Protein (ICOS) Controls T Helper Cell Subset Polarization after Virus and Parasite Infection," J. EXP. MED., 192(1):53-61 (2000)
	AAAA	Kuchroo et al., "B7-1 and B7-2 costimulatory molecules activate differentially the Th1/Th2 developmental pathways: Application to autoimmune disease therapy," CELL, 80:707-718 (1995)
	ABBB	Ling et al., "Cutting Edge: Identification of GL50, a Novel B7-Like Protein That Functionally Binds to ICOS Receptor," J. IMMUNOL., 164(4):1653-1657 (2000)
	ACCC	Mages et al., "Molecular cloning and characterization of murine ICOS and identification of B7h as ICOS ligand," EUR. J. IMMUNOL., 30(4):1040-1047 (2000)
	ADDD	Marguet et al., "cDNA Cloning for Mouse Thymocyte-activating Molecule," THE JOURNAL OF BIOLOGICAL CHEMISTRY, 267(4):2200-2208 (1992)
	AEEE	McAdam et al. (2000) "Mouse inducible costimulatory (ICOS) molecule expression is increased by CD28 costimulation and regulates development of Th2 cells," FASEB JOURNAL, 14(6):A1169
	AFFF	McAdam, "ICOS is critical for CD40-mediated antibody class switching," NATURE 409(6816):102-105 (2001)
	AGGG	McAdam, "Mouse Inducible Costimulatory Molecule (ICOS) Expression Is Enhanced by CD28 Costimulation and Regulates Differentiation of CD4 <sup>+</sup> T Cells," J. IMMUNOL., 165(9):5035-5040 (2000)
	AHHH	Mueller, "T cells: A proliferation of costimulatory molecules," CURR. BIOL. 10(6):R227-R230 (2000)
	AIII	Mullins et al. "Expression of the DBA/2J Ren-2 gene in the adrenal gland of transgenic mice" EMBO J., 8:4065-72 (1989)
	AJJJ	Mullins et al. "Fulminant hypertension in transgenic rats harbouring the mouse Ren-2 gene" NATURE, 344:541-44 (1990)

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	AKKK	Mullins et al. "Transgenesis in nonmurine species" Hypertension 22:630-33 (1993)
	ALLL	Niemann "Transgenic farm animals get off the ground" TRANSGENIC RESEARCH, 7:73-75 (1998)
	AMMM	Nojima et al., "The 4F9 antigen is a member of the tetra spans transmembrane protein family and functions as an accessory molecule in T cell activation and adhesion," CELLULAR IMMUNOLOGY, 152:249-260 (1993)
	ANNN	Overbeek "Factors affecting transgenic animal production," Transgenic Animal Technology, A Laboratory Handbook 96-98 (1994)
	AOOO	Özkaynak et al., "Importance of ICOS-B7RP-1 costimulation in acute and chronic allograft rejection," NATURE IMMUNOLOGY 2(7):591-596 (2001)
	APPP	Pech et al., "A large section of the gene locus encoding human immunoglobulin variable regions of the kappa type is duplicated," J. Mol Biol. 183(3):291-9 (1985)
	AQQQ	Poster, Kyoto International Conference Hall, Takaragaike Sakyo-ku, Kyoto, JAPAN (November 30, 1994) [ORIGINAL JAPANESE AND ENGLISH LANGUAGE TRANSLATION]
	ARRR	Redoglia et al., "Characterization of H4: a mouse T lymphocyte activation molecule functionally associated with the CD3/T cell receptor," EUR. J. IMMUNOL., 26(11):2781-2789 (1996)
	ASSS	Riley et al., "ICOS Costimulation Requires IL-2 and Can Be Presented by CTLA-4 Engagement," J. IMMUNOL., 166(8):4943-4948 (2001)
	ATTT	Robert et al., "Antibody Cross-Linking of the Thymocyte-Specific Cell Surface Molecule CTX Causes Abnormal Mitosis and Multinucleation of Tumor Cells," EXPERIMENTAL CELL RESEARCH, 235:227-237 (1997)
	AUUU	Sato et al. (2000) "Up-regulation of inducible co-stimulator (ICOS) expression and its regulation of cytokine production in inflammatory bowel disease," Gastroenterology, 118(4):A662
	AVVV	Sharpe, "Analysis of lymphocyte costimulation <i>in vivo</i> using transgenic and 'knockout' mice," CURRENT OPINION IN IMMUNOLOGY, 7:389-395 (1995)
	AWWW	Sigmund "Are studies in genetically altered mice out of control?" ARTERIOSCLER. THROMB. VASC. BIOL., 20:1425-29 (2000)
	AXXX	Swallow et al., "B7h, a Novel Costimulatory Homolog of B7.1 and B7.2, Is Induced by TNF $\alpha$ ," IMMUNITY, 11(4):423-432 (1999)
	AYYY	Tafuri et al., "ICOS is essential for effective T-helper-cell responses," NATURE 409(6816):105-109 (2001)
	AZZZ	Tai et al., "A role for CD9 molecules in T cell activation," J. EXP. MED., 184:753-758 (1996)
	AAAAA	Tamatani et al., "AILIM/ICOS: a novel lymphocyte adhesion molecule," INTERNATIONAL IMMUNOLOGY, 12(1):51-55 (2000)
	ABBBB	Tamatani et al., "Characteristics of an antibody which induces an ICAM-1-LFA-1-independent adhesion pathway," PROCEEDINGS OF THE JAPANESE SOCIETY FOR IMMUNOLOGY, Vol. 23, Abstract No. H-160 (1993) [ORIGINAL JAPANESE AND ENGLISH LANGUAGE TRANSLATION]
	ACCCC	Tezuka et al., "Genetic cloning of a lymphocyte surface signal transduction molecule which induces an unknown adhesion phenomenon," PROCEEDINGS OF THE JAPANESE SOCIETY FOR IMMUNOLOGY, Vol. 24, Abstract No. W17-14 (1994) [ORIGINAL JAPANESE AND ENGLISH LANGUAGE TRANSLATION]

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	ADDDD	Tezuka et al., "Identification and Characterization of Rat AILIM/ICOS, a Novel T-Cell Costimulatory Molecule, Related to the CD28/CTLA4 Family," BIOCHEM. BIOPHYS. RES. COMMUN., 276(1):335-345 (2000)
	AEEEE	Tomlinson et al., "The repertoire of human germline VH sequences reveals about fifty groups of VH segments with different hypervariable loops," J. Mol. Biol. 227(3):776-98 (1992)
	AFFFF	Wall "Transgenic livestock: progress and prospects for the future" THERIOGENOLOGY 45:57-68 (1996)
	AGGGG	Wang et al., "Costimulation of T cells by B7-H2, a B7-like molecule that binds ICOS," BLOOD, 96(8):2808-2813 (2000)
	AHHHH	Yoshinaga et al., "Characterization of a new human B7-related protein: B7RP-1 is the ligand to the co-stimulatory protein ICOS," INTERNATIONAL IMMUNOLOGY, 12(10):1439-1447 (2000)
	AIIII	Yoshinaga et al., "T-cell co-stimulation through B7RP-1 and ICOS," NATURE, 402(6763):827-832 (1999)

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